

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 16

[Docket No. 02N-0251]

Presiding Officers at Regulatory Hearings

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its administrative regulations governing who may act as a presiding officer at a regulatory hearing. This action would amend the regulations to permit an administrative law judge (ALJ) to act as a presiding officer and provide the appropriate delegations of authority. It is intended to increase the pool of qualified personnel available as presiding officers, thereby increasing the efficiency with which the agency conducts regulatory hearings, beginning with responding to hearing requests and continuing through issuance of written hearing reports. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on the proposed rule on or before *[insert date 75 days after date of publication in the **Federal Register**]*. If FDA receives any significant adverse comments, the agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will then proceed to respond to comments under this proposed rule using the usual notice-and-comment procedures.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

DMS
Display Date 8/14/02
Publication Date 8/15/02
Certifier C. Presley

FOR FURTHER INFORMATION CONTACT: Peter C. Beckerman, Office of the Chief Counsel (GCF-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7144.

SUPPLEMENTARY INFORMATION:

I. Discussion

As described in the related direct final rule, FDA's procedures for a regulatory hearing are set forth in part 16 (21 CFR part 16) of the agency's regulations. "Part 16 hearings" are offered under numerous statutory and regulatory provisions. Section 16.1 provides a list of statutes and regulations in which part 16 hearings are available.

Currently, § 16.42(a) provides that an FDA employee to whom the Commissioner of Food and Drugs (the Commissioner) delegates the authority, or any other FDA employee to whom such authority is redelegated, can serve as the presiding officer at a regulatory hearing. In turn, § 5.30(c) (21 CFR 5.30(c)) delegates authority to preside at and conduct a regulatory hearing to the Director of the Office of the Ombudsman for the agency; the Directors and Deputy Directors of the Center for Food Safety and Applied Nutrition, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research; Regional Directors; District Directors; the Director of the St. Louis Branch; and such other FDA official as the Commissioner may designate by memorandum in the proceeding.

FDA believes that the addition of the ALJ to the list of those delegated to conduct regulatory hearings would increase the pool of qualified personnel available to preside at regulatory hearings. In addition, by virtue of the nature of an ALJ's training and experience adjudicating disputes, FDA believes that an ALJ would be appropriately suited to conduct regulatory hearings. Therefore, the agency is proposing to amend §§ 5.30(c) and 16.42(a) to permit an ALJ to preside at and conduct regulatory hearings before the agency.

The regulations pertaining to ALJs issued by the Office of Personnel Management (OPM) (5 CFR 930.209(b)) provide that an agency may assign an ALJ, by detail or otherwise, to perform duties that are not the duties of an ALJ without prior approval by OPM when the duties are not

inconsistent with the duties and responsibilities of an ALJ, the assignment is not to last longer than 120 days; and the ALJ has not had an aggregate of more than 120 days of such assignments or details in the preceding year. However, OPM's regulations under 5 CFR 930.209(c) also state that on a showing that it is in the public interest, OPM may authorize a waiver from the 120-day limitation.

For the reasons already discussed, FDA believes it would be in the public interest to permit an ALJ to preside at and conduct part 16 hearings.

II. Additional Information

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule and the direct final rule are identical. This companion proposed rule will provide the procedural framework to finalize the rule in the event the direct final rule receives significant adverse comments and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends, and FDA intends the direct final rule to become effective 30 days after publication of the confirmation document. If FDA receives significant adverse comments, the agency will withdraw the direct final rule. FDA will proceed to respond to all the comments received regarding the rule, and if appropriate, the rule will be finalized under this companion proposed rule using usual notice-and-comment procedures.

For additional information, see the corresponding direct final rule published in the final rules section of this issue of the **Federal Register**. FDA will not provide additional opportunity for comment. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or

unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change.

III. Legal Authority

The broad rulemaking authority conferred on FDA by the U.S. Congress under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 201 *et seq.*) permits the agency to amend its regulations as contemplated by this proposed rule. Section 701(a) of the act (21 U.S.C. 371 (a)) gives FDA general rulemaking authority to issue regulations for efficient enforcement of the act.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order and in the other two statutes. This proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. The agency has considered the effect that this proposed rule would have on small entities. Because the proposed rule will amend only internal agency procedures, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531) requires that agencies prepare a written statement of anticipated costs and benefits before issuing any proposed or final rule "that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year * * *." This proposed rule imposes no Federal mandate that will result in such an expenditure. Therefore, FDA is not required to prepare a cost/benefit statement.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Request for Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. In the event the direct final rule is withdrawn, all comments will be considered comments on this proposed rule.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 5 and 16 are amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2 605; 7 U.S.C. 138a, 2217; 15 U.S.C. 638, 1261–1282, 1451–1461, 3701–3711a; 21 U.S.C. 61–63, 141–149, 301–394, 467f, 679(b), 801–886, 1031–1309, 1401–1403;

35 U.S.C. 156; 42 U.S.C. 238, 241, 242, 242a, 242l, 242n, 242o, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1, 300ar–25–28, 300cc, 300ff, 1395y, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

2. In § 5.28 revise paragraph (c)(1), redesignate paragraph (c)(10) as paragraph (c)(11), and add new paragraph (c)(10) to read as follows:

§ 5.28 Hearings.

* * * * *

(c) * * *

(1) The Director, Office of the Ombudsman, Office of External Relations, Office of the Commissioner.

* * * * *

(10) An Administrative Law Judge.

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**PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG
ADMINISTRATION**

3. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

4. Amend § 16.42 by revising paragraph (a) to read as follows:

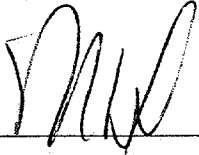
§ 16.42 Presiding officer.

(a) An FDA employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, or, consistent

with 5 CFR 930.209(b) or (c), an administrative law judge to whom such authority is delegated, may serve as the presiding officer and conduct a regulatory hearing under this part.

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Dated: 8/7/02
August 7, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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